DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

Unimax Medical Systems, Inc.
% Aemebiotechs Co., Ltd.
Mr. Michael Lee
No. 45, Minshen Road
Danshui Town – Taipei County
Taiwan 251, China

JUL 27 2015

Re: K111622
Trade/Device Name: Unimax Anti-Fog Solution
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: II
Product Code: OCT
Dated (Date on orig SE ltr): August 4, 2011
Received (Date on orig SE ltr): August 4, 2011

Dear Mr. Lee,

This letter corrects our substantially equivalent letter of September 9, 2011.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be

found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Benjamin R. Fisher -S

Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K111622

Device Name: Unimax Anti-Fog Solution

Indications for Use:

The Unimax Anti-Fog Solution is intended to be used to prevent "fogging" (caused by condensation) on the lenses of endoscopic/laparoscopic instruments which are likely to fog during use.

Prescription Use ___X___ AND/OR Over-The-Counter Use_____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Mark A. Ogle for MKM
(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K111622

SEP - 9 2011

K111622

510(k) Summary

5.1 Type of Submission: Traditional

5.2 Preparation Date: Jun 10, 2011

5.1 Revise Date: Jul 29, 2011

5.2 Submitter:

Address: 8F-2, No. 127, Lane 235, Pao Chiao Rd., Hsin Tien City, Taipei, Taiwan

Phone: 886-2-89191698

Fax: 886-2-89191528

Contact: Sophia Chiu

Establishment Registration Number: 3007791595

5.3 Identification of the Device:

Proprietary/Trade name: Unimax Anti-Fog Solution

Common Name: Anti-Fog Solution

Classification Name: Endoscope And/ Or Accessories

Device Classification: II

Regulation Number: 876.1500

Panel: Gastroenterology/Urology

Product Code: KOG

5.4 Identification of the Predicate Device:

Predicate Device Name: Xodus Medical Anti-Fog Solution

Manufacturer: Xodus Medical, Inc.

510(k) Number or Clearance Information: K063587

5.5 Intended Use and Indications for Use of the subject device.

The Unimax Anti-Fog Solution is intended to be used to prevent "fogging" (caused by condensation) on the lenses of endoscopic/laparoscopic instruments which are likely to fog during use.

5.6 Device Description

The Unimax Anti-Fog Solution is a clear / colorless, odorless, water soluble solution. The model with alcohol is comprised of DPGMME (=2%), Isopropyl alcohol (=6%), and Deionized water (=92%), while the model without alcohol is comprised of DPGMME (=2%) and Deionized water (=98%). Unimax Anti-Fog Solution functions by reducing the surface tension of water, thus preventing water droplets (fog) from forming on the lenses of endoscopic / laparoscopic instruments during use. This solution is bottled in a volume of 6cc's in a 10cc clear plastic dropper bottle. Included in the tyvek pouch packaging of this product is a 4.5*4.5*0.5 (L*W*H) adhesive backed, non-abrasive, x-ray detectable radiopaque/non-radiopaque, polyurethane foam pad for applying the product to endoscopic / laparoscopic lenses. This product is sold sterile to healthcare professionals only.

5.7 Non-clinical Testing

A series of safety tests were performed to assess the safety and effectiveness of the Unimax Anti-Fog Solution. The tests were conducted in accordance with **ISO 10993-1 Biological evaluation of medical devices- Part 1: Evaluation and testing, ISO 10993-5 Biological Evaluation of medical devices- Part 5: Test for in vitro cytotoxicity, ISO 10993-10 Biological evaluation of medical devices- Part10: Tests for irritation and delayed-type hypersensitivity, ISO 10993-12 Biological evaluation of medical devices- Part12: Sample preparation and reference material, ISO 11137-1: 2006 Sterilization of health care products - Radiation - Part 1: Requirements for development, validation, and routine control of a sterilization process for medical devices.** All the test results demonstrate Unimax Anti-Fog Solution meets the requirements of its pre-defined acceptance criteria and intended uses.

The results of the non-clinical testing demonstrate that the Unimax Anti-Fog Solution is as safe and effective as the predicate devices.

5.8 Safety and Effectiveness

The result of bench testing listed below indicates that the new device is as safe and effective as the predicate device:

- Fog Resistance Test
- Cleaning Ability Test
- Extractable Test
- Prolonged Fog Resistance Test

5.9 Substantial Equivalence Determination

The Unimax Anti-Fog Solution submitted in this 510(k) file is substantially equivalent in intended use, design, technology/principles of operation, materials and performance to the cleared Xodus Medical Anti-Fog Solution which is the subject of K063587. Differences between the devices cited in this section do not raise any new issues of safety or effectiveness.

Item	Proposed Device (Unimax Anti-Fog Solution)		Predicate Device (Xodus Medical Anti-Fog Solution)
Intended Use	The Unimax Anti-Fog Solution is intended to be used to prevent "fogging" (caused by condensation) on the lenses of endoscopic/laparoscopic instruments which are likely to fog during use.		Anti-Fog is intended to be used to prevent "fogging" (caused by condensation) on the lenses of endoscopic/laparoscopic instruments which are likely to fog during use.
Consisted Instruments	Bottled solution Foam pad		Bottled solution Foam pad
Models	With alcohol Alcohol free		With alcohol
Comprised Elements	With alcohol: DPGMME (=2%) Isopropyl alcohol (=6%) Deionized water (=92%)	Alcohol free: DPGMME (=2%) Deionized water (=98%)	Predominantly water (=95%) Surfactant (<5%) Isopropanol (<1%) Ethanol (<0.5%)

Dimension	Bottle: 10cc Foam pad: 4.5*4.5*0.5 (L*W*H)	Bottle: 10cc Foam pad: 13/4" x 1 ¼/2"
Sterilization	Gamma irradiation	Gamma irradiation
Safety standards	ISO 10993-1 ISO 10993-5 ISO 10993-10 ISO 10993-12	ISO 10993-1 ISO 10993-5 ISO 10993-10 ISO 10993-12
Performance standards	Not Applicable	Not Applicable

5.10 Conclusion

After analyzing bench tests, safety testing data, it can be concluded that Unimax Anti-Fog Solution is as safe and effective as the predicate device.